UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

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| DUANE EVANS, JR. and SHANNON EVANS,<br><br>Plaintiffs,<br><br>v.<br><br>BREG, INC.; LMA NORTH AMERICA, INC.; I-FLOW CORPORATION; DJO, LLC; DJO INCORPORATED; MCKINLEY MEDICAL LLC; MOOG INC.; CURLIN MEDICAL, INC.; STRYKER CORPORATION; STRYKER SALES CORPORATION; ADVANCED INFUSION, INC.,<br><br>Defendants. | Case No. 10-CV-00175<br><br>**AMENDED COMPLAINT AND JURY DEMAND** |

## PLAINTIFFS' AMENDED COMPLAINT AND JURY DEMAND

COME NOW Plaintiffs, DUANE EVANS, JR. and SHANNON EVANS, his wife, by and through their attorneys, and for their Complaint against the Defendants, allege and state as follows:

## PREAMBLE

1. Pain pumps are medical devices that surgeons have used to manage post-operative pain. Orthopedic surgeons have used pain pumps after surgery to deliver, by way of a catheter, continuous doses of pain relief anesthetic for several days directly into the shoulder joint.

2. The pumps first used in the 1990s had limited amounts of anesthetic, and surgeons placed the pain pump catheter in the muscle or outside the shoulder joint. Over the

years, however, the manufacturers increased the anesthetic capacity of the pumps (producing a higher volume of anesthetic delivery) and, with the knowledge and encouragement of the pain pump manufacturers, surgeons began to insert the catheter directly into the shoulder joint space.

3. Continuous injection of the post-operative anesthetics directly into the shoulder joint can cause serious and permanent damage to the shoulder joint cartilage. The damage occurs when the anesthetic kills the chondrocytes (cartilage cells) and causes cartilage to degenerate. The occurrence of this condition, as in patients injured by pain pumps, is called "chondrolysis", and can include the complete or nearly complete loss of cartilage in the shoulder joint. It is an irreversible and painful condition. Patients with this condition often require additional surgeries, which can include complete shoulder joint replacement. Medical literature indicates that "the prognosis for these shoulders is grim."[1]

4. The pain pump companies manufactured and marketed these devices without doing proper studies to determine the safety of high-volume pain pumps, or to determine whether or to what extent damage could result from the direct insertion of the pump's delivery catheter into the shoulder joint space. Instead the pain pump manufacturers encouraged orthopedic surgeons to use the pumps and anesthetics, in tandem, in what amounted to an untested and dangerous manner.

5. The pain pump manufacturers sought approval from the Food and Drug Administration (FDA) for the placement of the catheter in the shoulder joint space beginning

[1] Petty, D.H. *et al.*, *Glenohumeral Chondrolysis After Shoulder Arthroscopy*, Am. J. Sports Med. 32:(2)509 (2004).

in the late 1990s. However, based on a lack of study and/or documented safety information, the FDA *rejected* their applications for orthopedic and intra-articular placement. Yet, the pump manufacturers chose not to advise physicians about these dangers, not to advise patients of these risks, not to tell physicians that their FDA applications were rejected, and continued to sell and market these pumps without regard to the health impacts and residual effects the products would case to patients generally, and to Plaintiff, DUANE EVANS JR., in particular.

6. On November 13, 2009, the FDA issued a directive in which it noted that pain pumps and the anesthetics used in them were defective for their failure to warn regarding the risk of shoulder chondrolysis and directed pain pump and anesthetic manufacturers to include such warnings. The FDA further noted that the information on dose administration was insufficient in so far as there was no information about maximum daily dose or intra-articular use with pain pumps. Although this FDA directive was based upon reported adverse events of chondrolysis, this information was known or knowable to the pain pump and anesthetic manufacturers prior to the date Plaintiff, DUANE EVANS JR.', pump was manufactured, delivered and/or operatively installed in his shoulder.

7. On July 3, 2007, a group of surgeons, including prominent Orthopaedic Surgeon, Dr. Brent Hansen, published an article documenting some very disturbing findings. They reported a significant number of shoulder patients who had received intra-articular placement of a pain pump catheter developed chondrolysis, and stated that they had identified "a concerning and strong association between postarthroscopic chondrolysis and inter-articular pain pump catheter use", and "recommend[ed] that the use of intra-articular

pain pump catheters in combination with bupivacaine with or without epinephrine be avoided in all joints with an intact cartilage surface."[2] Prior published studies had discussed the condition of chondrolysis generally, however this was the first published study to suggest a direct link between the use of the pain pump delivery system and chondrolysis.

8. Had Defendants conducted those studies that the FDA requested and required back in the 1990s, and as they were obligated to do, they would have determined that exposure to pain pump anesthetics in the shoulder is dangerous and contraindicated. Further, and more importantly, had they performed the appropriate tests in a timely manner, and if they had not marketed and represented that pain pumps were safe and appropriate before they had actually determined them to be so, Plaintiff, DUANE EVANS JR., physician would not have used pain pumps in the joint space, and Plaintiff would not have suffered the shoulder injuries at issue herein.

## PARTIES

9. Plaintiffs, DUANE EVANS, JR. and SHANNON EVANS (hereinafter sometimes referred to as "Plaintiffs"), are citizens and residents of the State of North Carolina, residing at 11001 Morgan Creek Drive, Charlotte, North Carolina. Plaintiffs, at all times relevant hereto, were and continue to be husband and wife.

10. Defendant, BREG, INC. (hereinafter sometimes referred to as "BREG") is California corporation with its principal place of business located at 2611 Commerce Way, Vista, California 92081. At all times relevant hereto, BREG was engaged in Minnesota, in

[2] Hansen, B.P. *et al*., *Postarthroscopic Glenohumeral Chondrolysis*, Am. J. Sports Med. 35:1628-1634 (2007).

the testing, manufacturing, labeling, marketing, distribution, promotion, and/or sale of elastomeric infusion pain pumps.

11. Defendant, LMA NORTH AMERICA, INC. (hereinafter referred to as "LMA") is a Nevada corporation with its principal place of business located at 4660 La Jolla Village Drive, Suite 900, San Diego, California 92122. LMA acquired Breg's pain pump product line in April, 2008. LMA conducts regular and sustained business in Minnesota by selling and distributing its products in Minnesota and throughout the United States. On information and belief, LMA is the successor to Breg, Inc. Plaintiffs refer to LMA and BREG collectively as the "BREG Defendants."

12. Defendant, I-FLOW CORPORATION (hereinafter referred to as "I-FLOW"), is a Delaware corporation with its principal place of business at 20202 Windrow Drive, Lake Forest, California 92630. I-FLOW designs, manufactures and develops pain pumps. At all times relevant hereto, I-FLOW was engaged in Minnesota in the testing, manufacturing, labeling, marketing, distribution, promotion, and sale of elastomeric infusion pain pumps.

13. Defendants, DJO INCORPORATED and DJO, LLC (hereinafter sometimes collectively referred to as "DONJOY INC.", "DONJOY" or "DJO"), are Delaware corporations with their principal places of business located at 1430 Decision Street, Vista, California 92081. At all relevant times hereto, DONJOY was engaged in Minnesota in the marketing, distribution, promotion, and sale of pain pumps.

14. Defendant, MCKINLEY MEDICAL, LLC. (hereinafter sometimes referred to as "MCKINLEY"), is a Colorado corporation with its principal place of business located at 252 Clayton Street, Fourth Floor, Denver, Colorado 80206. MCKINLEY was purchased by

Defendant, MOOG INC., in August, 2006. At all relevant times hereto, MCKINLEY was engaged in Minnesota in the testing, manufacturing, labeling, marketing, distribution, promotion, and sale of pain pumps.

15. Defendant, MOOG INC. (hereinafter sometimes referred to as "MOOG"), is a New York corporation with its principal place of business located at Seneca Street and Jamison Road, East Aurora, New York 14052. MOOG is a global corporation that designs and manufactures various products, including medical devices and, specifically, pain pumps. MOOG, purchased Defendant, MCKINLEY, in August, 2006, and purchased the outstanding shares of Defendant, CURLIN MEDICAL, INC., in 2006. At all times relevant hereto, Defendant, MOOG ,was engaged in Minnesota in the testing, manufacturing, labeling, marketing, distribution, promotion, and sale of pain pumps.

16. Defendant, CURLIN MEDICAL, INC. (hereinafter sometimes referred to as "CURLIN"), is a Delaware corporation with its principal place of business located at 15751 Graham Street, Huntington Beach, California 92649. Curlin acquired assets of Defendant McKinley in August, 2006, including McKinley's pain pump business. At all times relevant hereto, Defendant Curlin was engaged in Minnesota in the testing, manufacturing, labeling, marketing, distribution, promotion, and sale of pain pumps.

17. Defendants, STRYKER CORPORATION, and STRYKER SALES CORPORATION, (hereinafter collectively referred to as "STRYKER") are Michigan corporations with their principal place of business at 2825 Airview Boulevard, Kalamazoo, Michigan 49002. At all times relevant hereto, the Defendants were engaged in Minnesota in

the testing, manufacturing, labeling, marketing, distribution, promotion and sale of pain pumps.

18. Defendant, ADVANCED INFUSION, INC. (hereinafter sometimes referred to as "Advanced Infusion"), is an Arizona corporation with its principal place of business at 290 S. Alma School Road, Suite 1, Chandler, Arizona 85224. At all times relevant hereto, Advanced Infusion, Inc. was engaged in Minnesota in the testing, manufacturing, labeling, marketing, distribution, promotion, and sale of elastomeric infusion pain pumps.

## JURISDICTION AND VENUE

19. This Court has diversity jurisdiction over the parties pursuant to 28 U.S.C. § 1332 insofar as the parties are citizens of different states.

20. Venue is proper in this jurisdiction pursuant to 28 U.S.C § 1391(a)(2) as the Defendants have each regularly solicited and engaged in business and other persistent courses of conduct in the State of Minnesota and derive substantial revenues from goods used and/or sold in the State of Minnesota. Defendants are corporations maintaining sufficient minimum contacts with this judicial district to subject the corporations to personal jurisdiction here.

21. The amount in controversy in this matter exceeds $75,000.00, exclusive of interest and costs.

## FACTUAL ALLEGATIONS

22. At all times material hereto, Plaintiff, DUANE EVANS JR., was a 31 year old man living in the State of New York when he consulted with an orthopedic surgeon, Kenneth Rauschenbach, D.O. of Hudson Valley Orthopaedic Surgery, P.C. in New York regarding

problems he was experiencing with his right shoulder. On or about February 17, 2006, on the advice and recommendation of Dr. Rauschenbach, Mr. Evans underwent arthroscopic surgery on his right shoulder at St. Luke's Cornwall Hospital, in Newburgh, New York.

23. During the course of the aforementioned surgery, Dr. Rauschenbach observed no significant degenerative changes of the glenohumeral joint.

24. A "pain pump" was inserted into the Plaintiff's shoulder joint by Dr. Rauschenbach during and/or at the close of the surgery, although the specific make and model pump used is not currently known to plaintiff as same is not identified with particularity by the hospital and/or physician's chart. Upon information and belief, the pain pump utilized was manufactured, labeled, marketed, distributed, promoted and sold by one or more of the defendants, BREG, INC.; LMA NORTH AMERICA, INC.; I-FLOW CORPORATION; DJO, LLC; DJO INCORPORATED; MCKINLEY MEDICAL LLC; MOOG INC.; CURLIN MEDICAL, INC.; STRYKER CORPORATION; STRYKER SALES CORPORATION; and/or ADVANCED INFUSION, INC.

25. The pain pump continuously injected anesthetic drug through a catheter emanating from the pump and implanted through the skin and into the plaintiff's which continuous infusion continued following the surgery.

26. Following the February 17, 2006 surgery, Plaintiff, DUANE EVANS JR., continued to experience symptoms in his right shoulder, including on-going pain and limited range of motion. As such, Plaintiff, DUANE EVANS JR., elected to seek a second opinion from another orthopaedic surgeon, Bradley Weiner, MD. of Catskill Orange Orthopaedics in Middletown, New York.

27. On September 6, 2006, Mr. Evans underwent a second arthroscopic surgery upon his right shoulder, performed by Dr. Weiner at Orange Regional Medical Center in Middletown, New York, during which Dr. Weiner observed that the anterior labral repair previously performed by Dr. Rauschenbach had "failed" and that the "visualization of the intra-articular contents was rather dramatic" with the "articular surface of the glenoid ... noted to be completely denuded of intact cartilage", "grade III changes throughout the entire glenoid with grade IV changes along the anterior and posterior rim". A "corresponding area of grade III/IV arthritic change" was also noted "along the articular surface of the humeral head".

28. No pain pump was utilized during and/or following the surgery performed on September 6, 2006.

29. Following the surgery on September 6, 2006, Plaintiff, DUANE EVANS JR., initially made some improvement, but had continued pain and limitations in the use of his shoulder by virtue of the condition of his shoulder joint and the loss of articular cartage therein and has suffered continued and additional injury.

30. The continuous injection of anesthetic drugs directly into Mr. Evans' shoulder joint after his February 17, 2006 surgery subsequently caused serious and permanent cartilage damage, which has caused and will cause him to suffer a complete or nearly complete loss of cartilage in the shoulder joint, and an irreversible and painful condition necessitating further and ongoing medical care and treatment, expenses associated therewith, physical and emotional pain and suffering, and related disability .

31. Due to the state of scientific knowledge, and the actions and/or inactions and conduct on the part of the defendants, as aforesaid, Plaintiff, DUANE EVANS JR., did not actually discover that the pain pump was the cause of the injury complained of herein until a date on or about November 8, 2008, nor could he have discovered same prior to July 3, 2007, when the first published link between pain pumps and damage to the articular cartilage in the shoulder joint appeared in the medical literature[3].

**FRAUDULENT CONCEALMENT**

32. Defendants' failure to document or follow up on the known defects in its product, concealment of known defects, failure to warn, and misrepresentations regarding use of the pumps in the joint space constitutes fraudulent concealment that equitably tolls applicable statutes of limitation.

33. Defendants are estopped from relying on the statute of limitations defense because Defendants actively concealed the defects, suppressed reports, failed to follow through on FDA notification requirements, failed to disclose known defects to physicians, and misrepresented information regarding use of the pumps in the joint space.

34. Defendants' conduct, as described in the preceding paragraphs, amounts to conduct purposely committed, which Defendants must have realized was dangerous, heedless and reckless, without regard to the consequences or the rights and safety of Plaintiff.

[3] Hansen, B.P. *et al*., *Postarthroscopic Glenohumeral Chondrolysis*, Am. J. Sports Med. 35:1628-1634 (2007).

## CAUSES OF ACTION

## COUNT I – NEGLIGENCE

35. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further allege:

36. At all times relevant to this action, Defendants had a duty to exercise reasonable care, and to comply with the existing standard of care, in the preparation, design, research, development, manufacture, inspection, labeling, marketing, promotion and sale of the pain pumps and the anesthetics used in the pumps, which the Defendants introduced into the stream of commerce, including a duty to ensure that users would not suffer from unreasonable, dangerous or untoward adverse side effects.

37. At all times relevant to this action, the Defendants had a duty to warn all health care providers and consumers of the risks, dangers, and adverse side effects of pain pumps and the anesthetics used in the pumps.

38. At all relevant times, the Defendants knew or reasonably should have known that the pain pumps were unreasonably dangerous and defective when used as marketed, directed and as designed, including but not limited to the following particulars:

a. Commonly used anesthetics likely to be used in pain pumps were harmful to human and animal articular cartilage, which toxicity to cartilage is increased with the duration of exposure;

b. Use of pain pumps with continuously injected anesthetic in the shoulder joint space had not been approved by the FDA and, in fact, the FDA had

specifically refused to approve such use given the state of knowledge and/or lack of testing to date;

c. Continuous injection of anesthetic through a catheter, directly into the shoulder joint, had not been adequately tested for safety or effectiveness; and,

d. The risk of damage to the cartilage, including the articular cartilage; narrowing of the joint space; chondrolysis; and/or other serious post-operative problems associated with using pain pumps to continuously infuse anesthetic into the joint space, as the Defendants had designed, marketed and instructed, outweighed any and all possible benefits of such use.

39. Defendants, and each of them, based on what was or reasonably should have been known, as described above, deviated from applicable standards of due care; and/or was/were each otherwise negligent in one or more of the following particulars:

a. In failing to conduct such tests and studies as may have been necessary to determine whether or not the use of pain pumps directly into the shoulder was safe prior to manufacturing, labeling, marketing, distributing and/or selling same for such use(s);

b. In failing to instruct or warn the medical community that the safety of the pain pump with continuously injected anesthetic had not been established for use in the shoulder;

c. In failing to disclose to the medical community that continuous injection of commonly used anesthetics such as lidocaine, mepivicaine, or Marcaine® ,

with or without epinephrine into the shoulder, in the manner delivered by the Pain Pumps, may cause serious and permanent injury to the joint cartilage;

d. In failing to include a precaution against placing the catheter of the pain pump into the joint space of the shoulder;

e. In failing to provide to the medical community adequate instructions for the safe use of the devices with continuously injected anesthetics;

f. In failing to disclose to the medical community that the effectiveness of pain pumps with continuously injected anesthetic was uncertain for use in the shoulder;

g. In failing to disclose to the medical community that adequate tests had not been done to determine the safety of using the pain pump in the shoulder;

h. In failing to disclose to the medical community that the tests requested by the FDA to determine the safety of using the pain pump in the shoulder had not been done;

i. In manufacturing a product to be used with continuously injected anesthetic, designed to directly inject into the shoulder commonly used anesthetics associated with damage to articular cartilage;

j. In manufacturing a product designed to deliver dangerously high doses of anesthetic drugs directly into the shoulder tissue and/or joint space; and,

k. In promoting pain pumps for the continuous infusion of anesthetics into the shoulder joint space after the FDA had considered and rejected such an indication for use thereof.

40. At all relevant times, Defendants knew or reasonably should have known that the manner in which they were infusing anesthetics via the pain pumps was unreasonably dangerous, and rendered the said pain pumps unreasonably dangerous and defective when used as directed, designed, labeled, marketed and sold, including but not limited to the following particulars:

a. Anesthetics which were intended and/or likely to be used in pain pumps were harmful and/or otherwise toxic to human and animal articular cartilage;

b. Use of pain pumps with continuously injected anesthetic in the shoulder joint space had not been approved by the FDA, and in fact had been specifically rejected by the FDA;

c. Continuous injection of anesthetic through a catheter connected to the Pain Pump and directly into the shoulder joint, in the manner intended, directed, marketed and/or which was otherwise foreseeable to the Pain Pump Defendants, had not been adequately tested for safety or effectiveness; and,

d. The risk of narrowing of the joint space, chondrolysis and other serious post-operative problems associated with using pain pumps with continuously injected anesthetic(s), as designed, intended, directed, marketed and instructed outweighed the possible benefits of such use.

41. The product defects alleged above were a substantial contributing cause of the injuries and damages suffered by Plaintiff, DUANE EVANS JR., which would not have occurred but for the use of the pain pump and/or the other acts and conduct on the part of Defendants, as outlined more fully herein above.

42. The injuries and damages suffered by Plaintiffs were a reasonably foreseeable consequence of Defendants' negligent acts and/or conduct.

43. Had Defendants performed those tests and studies necessary to determine that pain pumps and their anesthetics should not be used directly in the shoulder before Mr. Evans' physicians used a pain pump following his surgery, as they were was required to do, Mr. Evans would not have suffered the injuries and damages described with particularity above.

44. As a direct and proximate cause of Defendants' negligence, Plaintiff, DUANE EVANS JR., has and/or will be caused to suffer a permanent loss of cartilage in his right shoulder; associated pain and discomfort of the shoulder; loss of use and function of the right shoulder and arm; related medical care and treatment including surgery; physical and emotional pain, suffering, mental distress and anguish; and, other related damages according to proof.

## COUNT II – NEGLIGENT MISREPRESENTATION

45. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further allege:

46. Defendants, in the course of their business, negligently misrepresented and failed to disclose material facts concerning the risks which use of their pain pumps to deliver

anesthetics posed to patients, particularly those using the products for pain relief following shoulder surgery.

47. Defendants knew or should have known, given the presenting circumstances, including the absence of sufficient testing and/or data and the actions and conduct of the FDA, as outlined more fully herein above, that their representations concerning the purported safety and/or efficacy of their Pain Pumps, were false.

48. At all times material hereto, the actions, representations, and conduct, including active and or passive concealment, on the part of Defendants were made with the intent to induce reliance there, and to promote, market and sell pain pumps and/or anesthetics for what was and/or what amounted to an off-label use.

49. At all times material hereto, Defendants failed to exercise reasonable care or competence in obtaining or communicating truthful and accurate information concerning the Pain Pumps and the use thereof, including as a device to deliver a continuous infusion of anesthetics within the shoulder joint space, to Plaintiffs and Plaintiffs' physicians, and in so doing failed to comply with the existing and/or reasonable standards of care.

50. At all times material hereto, the Plaintiff, DUANE EVANS, and Plaintiffs' physicians reasonably and justifiably relied on Defendants aforementioned acts, conduct, misrepresentations and/or concealment(s), and as a direct and proximate result of such reliance, Plaintiff, DUANE EVANS JR., has and will continue to suffer the injuries, damages, and losses as alleged and described herein above.

## COUNT III – FRAUD

51. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further allege:

52. At all times material hereto, Defendants', by and through their respective employees, agents and sales representatives knowingly and intentionally made material misrepresentations to the Plaintiffs, Plaintiffs' physicians, and/or to the public at large, that pain pumps were a device which was safe and effective for the delivery of anesthetic following shoulder surgery such as Plaintiff, DUANE EVANS JR., underwent.

53. At all times material hereto, the representations by Defendants' employees, agents and sales representatives were in fact false, as pain pumps and the manner in which same delivered anesthetics following shoulder surgeries were not safe for human use and, instead, proximately caused damage to the cartilage of the shoulder joint, premature arthritis of the shoulder joint, narrowing of the joint space, glenohumeral chondrolysis and/or other related injuries and/or adverse side effects.

54. At all times material hereto, and specifically when Defendants' employees, agents and sales representatives made the representations aforesaid, Defendants knew said representations were false, fraudulent, deceptive, and/or otherwise misleading, and made same with the intent to defraud, deceive, and mislead and, in so doing, increase the volume of the sale of their product.

55. At all times material hereto, the Plaintiff, DUANE EVANS JR., Plaintiffs' physicians, and the public at large actually and justifiably relied upon the aforementioned acts, conduct and false and fraudulent misrepresentations of Defendants' employees, agents

and representatives, and reasonably believed said representations to be true and, in justifiable reliance upon these misrepresentations, said persons, including the Plaintiff, DUANE EVANS JR., were induced to prescribe, receive and/or use the pain pump for the continuous infusion of anesthetic following shoulder surgery.

56. As a direct and proximate result of the aforementioned false and fraudulent acts and conduct on the part of Defendants' employees, agents and sales representatives, Plaintiff, DUANE EVANS JR., has and will continue to suffer the injuries, damages, and losses as alleged herein.

57. Defendants' reckless and intentional concealment from Plaintiff and Plaintiff's physicians that pain pumps were not reasonably safe to deliver the continuous infusion of anesthetic to the shoulder joint following surgery, constituted conduct of an oppressive, extreme, malicious, fraudulent, and outrageous character, and was, in fact, of so extreme a degree as to extend beyond the realm of decency and is atrocious and utterly intolerable in a civilized community.

**COUNT IV – STRICT PRODUCT LIABILITY**

58. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further alleges:

59. At all times material hereto, Defendants placed their pain pump into the stream of commerce.

60. At all times material hereto, Plaintiff, DUANE EVANS JR., was given a pain pump for the continuous infusion of anesthetic following shoulder surgery, which product was used in a manner foreseeable to Defendants, as prescribed by his physician; and/or in a

manner consistent with how Defendants intended, promoted, marketed, labeled and/or manufactured said product to be used.

61. At all times material hereto, and specifically at such time as the Pain Pump used by the Plaintiff, DUANE EVANS JR., was manufactured, distributed, labeled, marketed and/or otherwise placed into the stream of commerce, said pump was in a defective and unreasonably dangerous condition such that the foreseeable risks associated therewith exceeded the benefits associated with its design and/or formulation. Alternatively, the pain pumps manufactured and/or supplied by Defendants were defective in design or formulation, in that when it/they left said Defendants' hands, they were unreasonably dangerous and more dangerous than an ordinary consumer would expect. Examples of the unreasonably dangerous and defective condition(s) at issue include, but are not necessarily limited to, one or more of the following:

a. The pain pumps lacked sufficient or adequate warning(s) and/or clinical trials, testing and study, and reporting regarding the results of such studies; and,

b. The pain pumps lacked adequate pre- and post-marketing warning or instruction to the medical community and/or to patients.

62. At all times material hereto, the pain pump manufactured, labeled, distributed and/or marketed by Defendants, was expected to and did in fact reach the Plaintiff, DUANE EVANS JR., without substantial change in condition.

63. The defective and/or unreasonably dangerous condition of the pain pump(s) which Defendants manufactured, designed, distributed, tested, sold, marketed, advertised

and/or promoted, was a substantial factor in bringing about the injuries and/or damages to the Plaintiff, DUANE EVANS JR., as aforesaid and proximately caused the same.

**COUNT V – STRICT LIABILITY - FAILURE TO WARN**

64. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further allege:

65. At all times material hereto, Defendants manufactured, designed, distributed, labeled, advertised, promoted and placed into the stream of commerce certain pain pumps, including the pump received by and/or used by the Plaintiff, DUANE EVANS JR., which were in a defective and unreasonably dangerous condition such that the foreseeable risks associated therewith exceeded the therapeutic benefits associated with the design and/or formulation of said product(s).

66. At all times material hereto, Defendants' pain pumps were unreasonably dangerous and defective in ways which included, but are not necessarily limited to, one or more of the following:

a. due to inadequate warning and/or inadequate clinical trials, *in vivo* and *in vitro* testing and study, and inadequate reporting regarding the results;

b. due to inadequate post-marketing warning or instruction to the medical community and to patients, including Plaintiff, DUANE EVANS JR.;

c. due to Defendants' continued marketing, labeling and/or promotion of said products as safe and effective when same were and/or reasonably should have been known to Defendants not to be so.

67. At all times material hereto, the defective warning(s) associated with the pain pump was/were a substantial factor in bringing about injury/ies to Plaintiff, DUANE EVANS JR., as aforesaid.

68. As a direct and proximate cause of the defective condition of Defendants' pain pumps, specifically the failure to warn, together with such other actions, inaction, negligence, carelessness, and/or wrongdoing as described herein above, Plaintiff, DUANE EVANS JR., was caused to suffer injury and related damage as described with particularity above.

**COUNT VI BREACH OF IMPLIED WARRANTY**

69. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further allege:

70. On or about February 17, 2006, Plaintiff, DUANE EVANS JR., purchased and/or ultimately obtained a pain pump from Defendants, or one of them, in connection with his shoulder surgery described more fully herein above.

71. At all times material hereto, Defendants, and each of them, impliedly warranted that their pain pumps were of merchantable quality and safe and fit for the use for which they were intended, manufactured, marketed, distributed, labeled and/or promoted, which uses specifically included continuous infusion of post-surgical anesthetics within the shoulder joint.

72. At all times material hereto, Plaintiff, DUANE EVANS JR., reasonably and justifiably relied on the skill, judgment, representations and implied warranty of Defendant(s) that the pain pump manufactured by same was of merchantable quality and was otherwise safe and fit for the use for which they were intended, including those described more fully above.

73. Contrary to Defendants' implied warranty, the pain pump was not of merchantable quality and was not safe nor fit for the use(s) aforesaid, in that said pump(s) had serious, undisclosed risks of harm and/or other dangerous propensities when put to their intended and/or foreseeable use(s), and were likely to cause severe injuries to users of the pain pump, including the Plaintiff, DUANE EVANS JR. and, as such, a breach of said implied warranty occurred.

74. As a direct and proximate result of Defendants' breach of implied warranty, as aforesaid, Plaintiff, DUANE EVANS JR., has and will continue to suffer injuries, damages, and related losses as alleged and described more fully herein above.

**COUNT VII – LOSS OF CONSORTIUM**

75. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein at length and further allege.

76. At all times material hereto, Plaintiffs DUANE EVANS, JR., and SHANNON EVANS, were and continue to be husband and wife.

77. As a further direct and proximate result of the acts and conduct on the part of Defendants complained of herein, and the injuries and related damages suffered by Plaintiff, DUANE EVANS, JR., as aforesaid, Plaintiff, SHANNON EVANS, has suffered and will

continue to suffer loss of consortium and the care and comfort of her husband's society; has suffered and will continue to suffer in the future, mental anguish, the loss of support, love, companionship, affection, society, sexual relations, solace and other damages.

78. Accordingly, Plaintiff, SHANNON EVANS, seeks and is entitled to compensatory damages in an amount to be determined at trial.

## PRAYER FOR RELIEF

**WHEREFORE**, Plaintiffs pray for judgment against each of the Defendants as follows:

a. Economic and non-economic damages and damages for pain and suffering and loss of basic and pleasurable activities in an amount in excess of $75,000 as provided by law and supported by evidence at trial;

b. For compensatory and other damages according to proof;

c. For disgorgement of profits;

d. For an award of attorneys' fees and costs;

e. For prejudgment interest and the costs of suit; and

f. For such other and further relief as this Court may deem just and proper.

## JURY DEMAND

Plaintiffs each hereby demand a jury trial on all claims so triable in this action.

Dated: January 22, 2010

s/Yvonne M. Flaherty

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